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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,238	05/09/2001	Graham P. Allaway	51320-AB/JPW/SHS	4501

7590 09/10/2004

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/852,238	ALLAWAY ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 08/13/2001, 06/18/2004 01/28/2002
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: sequence letter

DETAILED ACTION

Amendment filed on May 09, 2001 has been entered and claims 1-48 have been canceled. New claims 49-5 have been added. The previous Office Action on Restriction/Election for those claims are vacated. The examiner Apologized for the office properly scanning the preliminary amendment into a wrong index of the electronic file.

Claims 49-55 are pending and considered before the examiner.

Sequence requirements

This application contains sequence disclosure on **Table 4 of page 45** that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

Priority

1. This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading "This is a continuation of Application No. 09/724,105, filed 11/28/2000, which is a continuation of Application No. 08/874, 618, filed 06/13/1997", which claimed benefit of provisional application No. 60,019,941, filed on 06/14/1996 should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

3. Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. The claimed invention of claims 49-51 and 53 are directed to non-statutory subject matter. The invention of claims 49, 50, 51 and 53 read on a polypeptide encoding a CCR5 chemokine receptor. A chemokine receptor is a product of nature. Accordingly, claims 49-51 and 53 are directed to a subject matter, which are considered to be non-statutory and non-patentable subject matter within the scope of 35 U.S.C. 101. See Official Gazett, 1077 O.G. April 21, 1987. Amending claims by incorporating the claim language, " isolated or synthesized" would overcome this rejection.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 51 recites the limitation "the original consecutive amino acids" in 49 and 50. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 51 is unclear in that it fails to define which consecutive amino acids in a CCR5 receptor is referred as original consecutive amino acids. The CCR5 receptor has more than 350 amino acid residues, and it contains several variants according to the state of art. Claims 49 and 50 only recite 31 consecutive amino acid residues in the N-terminal amino acid sequence of a CCR5 receptor. Claims 49 and 50 does not recites or define any original amino acids.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 55 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

11. The test of scope of the enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art would undue experimentation (See United States v. Theketronic Inc., 8USPQ2d 1217 (fed Cir. 1988). Whether undue experimentation is required is based upon on weighting many factors. outlined in Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in re Wands, 8USPQ2d 1400 (Fed. Cir. 1988) set forth bellow:

12. 1) & 20 State of art and Unpredictability of the field. The complete CCR5 sequence structure is known in the art. The approach for utilizing CCR5 antagonist to block HIV entry in order to inhibit HIV infection has been studied in this filed. However, it is still unpredictable and questionable for using this approach to get any therapeutic benefit for inhibition of HIV infection as evidenced by Dettin et al. (Biochem Biophys Res Commun. 2003 Aug 1;307(3):640-646). Dettin et al. disclose that CCR5 to mediate the entry of R5-HIV-1 strains into target cells. The N-terminus of CCR5, which contains several sulfated tyrosines, which plays a critical role in gp120–CCR5 binding and, consequently, in viral entry. However administration of such tyrosine sulfated peptide, and its unsulfated analogue, and a point-mutated peptide are unable to inhibit R5-HIV-1 mediated infection. Surprisingly, these peptides show the capability of enhancing HIV-1 infection caused by X4 strains through the up-regulation of both CD4 and CXCR4 receptors (see entire document, especially pages 640-644, Figs. 1-4).

13. 3) & 4) working examples and Amount of guidance. The specification only teaches on page 74 that synthetic peptides representing the four extracellular domains of CCR5 inhibit the HIV-1 envelope protein gp120-mediated membrane fusion in an in vitro assay. The specification does not presents any working examples of the claimed invention, e.g. who they use such peptides inhibit the HIV infection in vitro and in vivo.

14. 5) Scope of the claims. The broad scope claimed invention read on inhibit the HIV infection in vivo and in vitro.

15. 6) & 7) Nature of the invention and Lever of the skill in the art. The invention involves one of the most complex and unpredictable fields of treating HIV infection. The level of the skill in the art is very high. As noted by some of the preeminent researchers in this field supra, significant hurdles remain to be overcome in order for the skilled artisan to practice successful gene therapy.

16. Given the above analysis of the factors, which the courts have determined, are critical in asserting whether a claimed invention is enabled, it must be considered that the skilled artisan would have to conduct undue and excessive experimentation in order to practice the claimed invention.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 49-54, and 55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 11, 13, 43, 48 of

copending Application No. 09,724, 105. This is a provisional obviousness-type double patenting rejection.

19. Claims 49-54 and 55 are directed to a polypeptide comprising a portion of a chemokine receptor, CCR5 or and a composition as well as a method comprising same. The chemokine receptor is able to effectively inhibit the fusion between the HIV-1 virus or HIV-1 infected cells and $CD4^+$ cell hereby inhibit the HIV-1 infection. The method comprises contacting the CD4+ cells with the chemokine receptor polypeptide, then inhibit the HIV-1 virus or HIV-1 infected cells and $CD4^+$ cell hereby inhibit the HIV-1 infection

20. Claims 1, 11, 13, 43, 48 of copending Application No. 09,724, 105 are also directed to a polypeptide or a method of using the polypeptide for treating HIV-1 infection. The polypeptide has sequence corresponding to a portion of a chemokine receptor or it is a receptor CCR5 (claim 37), which is capable of inhibiting the fusion of HIV-1 to CD4+ cells without substantially affecting the said chemokine receptors capacity to bind to chemokine, and thus inhibiting HIV-1 infection to the cells.

21. While the conflict claims are not identical, the scopes of conflict claims are overlapping. For example, the scope of claims 1, 11, 13, 43, 48 of copending Application No. 09,724, 105 broadly read on any polypeptide including a part of a chemokine receptor or complete sequence of chemokine receptor CCR5 and a method of using same, which will encompasses the scope of claims 49-53, which read on a polypeptide and method of using the polypeptide since the polypeptide as the claims drafted comprises at least part of the chemokine receptor CCR5.

22. Therefore, it would have been obvious for a person skill in the art to claim a species of chemokine receptor of claims 1, 11, 13, 43, 48 of copending Application No. 09,724, 105 and use it as a treatment composition for HIV-1 infected subject since it is already tested and approved in Application No. 09,724, 10 that the said polypeptide has an inhibitory effect in turn of fusion between the HIV-1 or HIV-1 infected cells with CD4+ cells, thus inhibiting the HIV-1 infection without unexpected result.

Claim Rejections - 35 USC § 102

23. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

24. A person shall be entitled to a patent unless –

25. (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

26. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

27. Claims 49 and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Li et al. (US Patent SN. 6,025,154A).

28. Li et al. disclose an amino acid sequence of a G-protein coupled chemokine receptor, SEQ ID NO: 2. This sequence at its amino terminal amino acid sequence (N-terminal) comprises a consecutive 10 amino acid residues that is 100% identical to the portion of the claimed amino terminal sequence of CCR5 chemokine receptor, SEQ ID NO: 5 in the current application. Moreover, the whole amino acid sequence also differs from the SEQ ID NO: 5 in its N-terminal in that it contains a single amino acid mutation at the amino acid position no. 21. Therefore, the rejected claims are anticipated by the cited reference.

29. Claims 49-51 and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Li et al. (US Patent SN. 6,511,826B).

30. Li et al. disclose an amino acid sequence of a CC chemokine receptor, SEQ ID NO: 9, which comprises an amino terminal sequence of a consecutive 31 amino acid residues that is 100% identical to the claimed CCR5 chemokine receptor amino terminal sequence, SEQ ID NO: 5. Therefore, the claimed invention is anticipated by the cited reference.

31. Claims 49-51 and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Gary et al. (US Patent SN. 6,265,184B1).

32. Gary et al. disclose an amino acid sequence of a CC chemokine receptor, which comprises an amino terminal sequence of a consecutive 31 amino acid residues that is 100% identical to the claimed CCR5 chemokine receptor N-terminal sequence, SEQ ID NO: 5. Therefore, the claimed invention is anticipated by the cited reference.

33. Claims 49-51 and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Littman et al. (US Patent SN. 6,258,527B1).

34. Littman et al. disclose an amino acid sequence of a CC chemokine receptor designated as CC-CKR5, SEQ ID NO: 14 (Now it is named CCR5), which comprises an amino terminal sequence of a consecutive 31 amino acid residues that is 100% identical to the claimed CCR5 chemokine receptor amino terminal sequence, SEQ ID NO: 5. Therefore, the claimed invention is anticipated by the cited reference.

Claim Rejections - 35 USC § 102

35. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

36. A person shall be entitled to a patent unless –

37. (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

38. Claims 49-51 and 53 are rejected under 35 U.S.C. 102(a) as being anticipated by Samson et al. (Biochemistry 1996, Vol. 35, pp. 3362-3367).

39. Samson et al. disclose an amino acid sequence of a new CC chemokine receptor, Human ChemoR13, later designated as CC-CKR5, now named as CCR5 (Fig. 1 on page 3364), which comprises an amino terminal sequence of a consecutive 31 amino acid residues that is 100% identical to the claimed CCR5 chemokine receptor amino terminal sequence, SEQ ID NO: 5. Therefore, the claimed invention is anticipated by the cited reference.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li
Art Unit 1648
08/29/2004

James C. Housel 9/7/04

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Notice to Comply	Application No.	Applicant(s)	
	Examiner	Art Unit	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Table 4 on page 45 needs to comply with the sequence rule

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
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